

## REMARKS

### Status of the Application

Claims 1-4, 6-19, and 21-23 are pending in the application.

Claims 1-4 and 6-12 have been rejected under 35 USC § 112, first paragraph.

Claims 1-4, 6-12, 14-19, and 21-23 have been provisionally rejected for obviousness-type double-patenting over claims 1-2 and 5-13 of copending, commonly assigned U.S. patent application Serial No. 11/411,531.

Claims 1-4, 6-12, 14-19 and 21-23 have been rejected as obvious over Osborn (U.S. 3,212,495) in view of Van Dyke (U.S. 6,316,598).

With this response, claims 21-23 have been renumbered as claims 20-22, as noted at page 10 of the Office action. Additionally, claims 1, 2, 4, 6-10, 12, 14-17 and 20-22 (as renumbered) have been amended to obviate the Section 112 rejections and to further patentably distinguish over the prior art of record. Claim 13 has been canceled. Applicants reserve the right to pursue the canceled subject matter in one or more subsequent applications. New claims 23-26 have been added.

After entering the amendments identified herein, claims 1-4, 6-12, and 14-26 will be pending.

### Response to Claim Rejections

#### *The Double-Patenting Rejections*

A Terminal Disclaimer disclaiming the terminal part of any patent granted on the present application that extends beyond the statutory term of any patent granted on copending, commonly assigned U.S. patent application Serial No. 11/411,531, is submitted herewith to obviate the provisional obviousness-type double patenting rejections.

#### *The § 112 Rejections*

With respect to the Section 112 rejections, applicants have deleted the phrase “solely by” and have instead adopted the formulation proposed by the Examiner and his supervisor in copending, commonly assigned U.S. patent application Serial No. 11/411,531, during the

telephonic interview conducted in that case on September 3, 2009. As described throughout the specification of the present application, for example, at paragraph [0028] of the published application, electrostatic forces are the only mode described for causing the biologically active substance to adhere to the support. In view of the process limitations added by this amendment to claims 1 and 14, applicants respectfully submit that the Section 112, first paragraph rejections have been obviated.

### ***The §103 Rejections***

Claim 1 has been amended to reflect the subject matter deemed allowable in co-pending U.S. application 11/411,531, and now recites that the inventive skin patch comprises “a support *having an electrically charged surface resulting from the application to the support of an ionizing field*” having an organic allergen bound through electrostatic forces to the support. Support for these amendments is found in the published specification, for example, at paragraphs [0028] and [0037] to [0038].

Claim 1 also has been amended to further specify that the inventive skin patch comprises “*a preselected amount of an organic allergen in the form of individualized or agglomerated dry particles*.” This feature distinguishes the ready-to-use skin patch of the present invention from the prior art systems, which required that the allergen be prepared extemporaneously and loaded onto the skin patch, usually in liquid form, immediately prior to application to prevent the allergen from losing its reactogenicity. This led to variability in the amount of the applied allergen in previously-known systems, with potentially misleading results. Support for the foregoing amendments is found in the published specification, for example, in paragraphs [0025], [0030] and [0036].

Similar amendments have been made to independent claim 14, based on the same support in the present application.

None of the cited prior art of record teaches or suggests the invention set forth in the amended claims. Osbourn is cited as disclosing a “plurality of test strip articles” for testing sensitivity to various substances, and which include adhesive regions. The Office action states at page 6 that “Osbourn does not teach keratin *per se* but the motivation is reasonably present in view of the optimizations of Osbourn drawn to various substances to be tested for sensitization.” Applicants note that “keratin” is not mentioned in their application. Moreover, as described

below with respect to Van Dyke, keratin is an *inert* substance that may be used to absorb urine, menses or exudate. Applicants submit that there would have been no motivation for one of ordinary skill to place keratin (by itself) on a skin allergy test patch, but even doing so would not yield applicants' claimed invention.

Osbourne teaches the use of an *absorbent pad* onto which an allergen – in a liquid or dissolved form – may be deposited. Col. 2, lines 8-10, lines 48-54 and lines 63-66; col. 3, lines 32-36 and lines 66-70; and element “a” of claim 1: “a pad of absorbent material for holding a test substance to which said skin may be sensitive” (emphasis added). Osbourne does not teach or suggest adhering a powdered dry organic allergen to the absorbent pad using electrostatic forces, much less applying an ionizing field to a substrate to create an electrically charged surface to which an organic allergen adheres by electrostatic forces as recited in the amended claims.

Van Dyke is cited in the Office action as teaching a method of preparing keratin for use in baby diapers, tampons, and to absorb exudate in wound treatment systems. Contrary to the contention at page 7, line 11 and page 8, lines 16-18 of the Office action, Van Dyke does not teach that keratin is itself antigenic as contended in the Office action, but rather the opposite – that it is an inert substance – a “non-toxic, *non-antigenic* product.” Col. 1, lines 52-56 (emphasis added) and col. 11, lines 9-13. Van Dyke teaches that keratin can be manufactured in a powdered form, so that when it contacts urine, menses or exudate, it forms a stable, non-toxic and non-antigenic hydrogel that will not leach onto and irritate the skin. Col. 1, line 65 to col. 2, line 14; col. 3, lines 39-65. As acknowledged in the Office action at page 8, lines 19-21, Van Dyke does not teach or suggest using a keratin powder or hydrogel as a component of a skin test patch. Van Dyke also would not have suggested to one of skill in the design of skin test patches that a powder (whether a hydratable keratin or for that matter anything else) could or should be adhered to a skin test patch substrate by electrostatic forces arising from an electrical charge that is impressed on the substrate by applying an ionizing field to the substrate during manufacture.

Applicants respectfully submit that neither Osbourne nor Van Dyke, nor any of the other prior art of record, describe a skin patch including “a support having an *electrically charged surface resulting from the application to the support of an ionizing field*” and that permits “a preselected amount of an organic allergen [] in the form of individualized or agglomerated dry particles [to be] *bound to the electrically charged surface through electrostatic forces...*” as recited in the amended claims. Neither does either reference provide any teaching regarding

making a skin patch pre-loaded with a preselected amount of an organic allergen. On the contrary, Osbourn teaches the use of a cellulose pad which (like the prior art discussed in paragraphs [0011] to [0027] of the present application) is loaded with an inherently variable amount of allergen immediately prior to application of the patch. *See* Osbourn at col. 3, lines 33-41.

Thus, for at least the reasons given above, neither amended claim 1 nor 14, nor any claim depending therefrom, is obvious over Osbourn in view of Van Dyke.

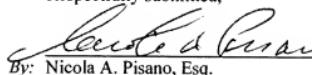
### **Conclusion**

For at least the reasons given above, applicants submit that this application is condition for allowance. Applicants request that the Examiner call the undersigned if a telephone call could help resolve any remaining items.

No fees are believed due at this time. However, please charge any required fees, or credit any overpayments, to Jones Day Deposit Account No. 50-3013.

Respectfully submitted,

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By: Nicola A. Pisano, Esq. 34,408  
(Reg. No.)  
**JONES DAY**  
222 East 41st Street  
New York, New York 10017-6702  
(858) 314-1200